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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/201,916 | 12/01/98 | HOPE R | DYOU17.001AU |

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| EXAMINER | |
|---|---|
| ZEMAN, R | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | 19 |

**DATE MAILED:** 08/21/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/201,916 | Hope et al. |
| **Examiner** | **Art Unit** |
| Robert A. Zeman | 1645 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Jun 11, 2000* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-6, 17, and 22-25* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6, 17, and 22-25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

The amendment filed on 6-11-2001 is acknowledged. Claims 1-6 and 17 have been amended. Claims 7 and 18 have been canceled. Claims 22-25 have been added Claims 1-6, 17 and 22-25 are pending and currently under examination.

### *Claim Rejections Withdrawn*

### *35 USC § 112*

The rejection of claims 1-3 and 6-7 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the targeting sequence comprising a hepatitis C virus (HCV) core protein and the targeting sequence comprising amino acids 125-144 and 161-166, does not reasonably provide enablement for "all fragment, derivatives, variants, or homologues thereof" is withdrawn, in part, in light of the amendment thereto. The amendment is sufficient to overcome the rejection with regard to "fragments" of a HCV core protein but not with regard to HCV core protein derivatives, variants or homologues. The cancellation of claim 7 renders the aforementioned rejection moot.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "capable of" is withdrawn in light of the amendment thereto .

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "affecting" is withdrawn in light of the amendment thereto .

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "expressed" is withdrawn in light of the amendment thereto .

The rejection of claims 3 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "administering" is withdrawn in light of the amendment thereto .

The rejection of claims 3 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "the susceptibility of the cell to viral infection or the effects of viral infection" is withdrawn in light of the amendment thereto .

The rejection of claims 4 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "and/or" is withdrawn in light of the amendment thereto .

***Claim Rejections Maintained***

***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, and 22-23 are rejected under U.S.C. 112, first paragraph, for the reasons outlined in the rejection of claims 1-3 and 6-7 in the previous Office action. Said rejection was made because the specification, while being enabling for the targeting sequence comprising a hepatitis C virus (HCV) core protein and the targeting sequence comprising amino acids 125-144

and 161-166, does not reasonably provide enablement for "all fragments, variants, or homologues thereof". The amendment is sufficient to overcome said rejection with regard to "fragments" of a HCV core protein but not with regard to HCV core protein derivatives, variants or homologues.

Applicant argues:

1. Specification states HCV core protein fragments of the invention contain both amino acids 125 to 144 and 161 to 166. Said regions are the lipid binding regions of the HCV core protein.

2. Specification discloses different methods of obtaining variants and homologues of the HCV core protein sequence.

3. Specification teaches how to identify or produce a variant.

4. A homologue could be identified by assessing percent homology within identified regions.

Applicant's arguments have been considered and deemed non-persuasive.

- With regard to Applicant's assertion that the specification teaches methods for obtaining variants and homologues of the HCV core protein, the passages cited by Applicant do not recite method steps but merely contain prophetic statements.
- In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. percent homology as methodology for determining homologues, ) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Consequently, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification fails to teach how to make and any HCV core protein derivatives, variants or homologues. The specification merely states that they may be used.

Claims 1-6, 17 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, for the reasons outlined in the rejection of claims 1-7 and 17-18 in the previous Office action. Said rejection was made because the specification, while being enabling for a method of identifying a substance which disrupts the interaction between a lipid globule targeting sequence and a lipid globule and determining whether said substances reduces or abolishes the susceptibility of **liver cells** to **hepatitis C virus (HCV)** or the effects of HCV infection on said cells , does not reasonably provide enablement for determining whether said substance reduces or abolishes the susceptibility of any other viral infection in any other cell type.

Applicant argues:

1. The amendment indicates that the susceptibility is to HCV or any virus which uses lipid molecules and the target cells are any cells that are infected by these viruses.

2. HCV does not target just liver cells.

Applicant's arguments have been fully considered and are deemed non-persuasive.

- The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the amended claims. The specification discloses that the HCV core protein binds with lipid globules resulting in the diffusion of the lipid granules present in liver cells. The specification also discloses an inferred relationship between ADRP and lipoproteins in liver cells based on the observation that an increased level of HCV core protein results in a reduced level of ADRP. Based on this information the Applicant concludes that the disruption of the interaction between the lipoproteins and the HCV core protein would reduce the effects of HCV infections. **The specification does not disclose a similar relationship between proteins of any other virus and lipoproteins and/or ADRP nor does it disclose a similar relationship between HCV core proteins, lipoproteins and/or ADRP in other cell types**. Consequently it would be impossible for anyone to practice the claim invention.

Claims 5, 17 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, for the reasons outlined in the rejection of claims 5 and 17-18 in the previous Office action. Said claims were rejected as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The aforementioned claims are drawn to a method of identifying

substances that treat or prevent a viral infection by upregulating the expression of adipocyte-specific differentiation related protein (ADRP) in mammalian cell.

Applicant argues:

1. Specification provides extensive proof that ADRP is involved in prevention or reducing symptoms of an infection.

2. Applicant cites passages of the specification which recite that ADRP levels correlate with the presence of an HCV infection and that ADRP levels consistently decreased when HCV was present in the cell.

3. One of skill in the art would understand that a substance that increased ADRP levels would correlate with a decrease or inability to detect HCV.

- People of skill in the art require factual evidence, that a benefit can be derived by the therapeutic application of a substance. The instant specification fails to provide any evidence that any substance identified by methods instantly disclosed, would prevent or elicit a therapeutic response in a viral infection. Moreover, that ADRP levels in fact play a role in viral infections or disease progression. Since neither the art nor the specification indicates that any benefit to the treated subject would be obtained from substances identified by the claimed method, it would be impossible for one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the claimed invention. The passages cited by Applicant merely describe *in vitro* assays that demonstrate a

tentative association between ADRP levels and HCV infection. This does not correlate to a therapeutic or preventative effect *in vivo.* There is no evidence that the putative relationship between HCV and ADRP levels observed *in vitro* even exists in the complex biological environment of a living animal.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 6, 17 and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons outlined in the previous Office action in the rejection of claims 1-7 and 17-18.

The rejection of claims 1-3 and 6 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the terms "homologues" and "variants". The amendment is insufficient to overcome the rejection. Applicant fails to define what is meant by a "variant". The specification is silent on what percentage of divergence is required to be considered a variant and at what point does a "variant" become totally unrelated. The specification is equally deficient in defining what is meant by a "homologue". Applicant fails to disclose what percentage of the total protein must be present in order for a polypeptide to be considered a "variant" of said HCV

protein or what processes must be utilized to generate "derivatives" or "homologues" of said HCV protein. Additionally, the specification is silent with regard to what biochemical/immunological/physical properties must be present in order for a protein to be considered a "variant" or "homologue". Consequently, it would be impossible for one of skill in the art to ascertain what would fall under the categories of "variant" or a "homologue".

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "administering" is maintained for reasons of record. The amendment is insufficient to overcome the rejection. It is still unclear what methodologies are employed in order to "administer" a virus to cells. The amendment merely clarifies the "substance" that is being "administered".

The rejection of claims 5, 17 and 24-25 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite for failing to recite the active method steps to perform the claimed invention is maintained for reasons of record. The amendment is insufficient to overcome the rejection. The active step "identifying whether the administration of said substance upregulates expression of ADRP" does not correlate with the preamble of the claim "A method of identifying a substance for treating or preventing the effects of an infection.....".

*Conclusion*

No claim is allowed.

Claims 1-6, 17 and 22-25 are free of the art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

LYNETTE R. F. SMITH
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Robert A. Zeman

August 14, 2001